STATE OF WISCONSIN

DEPARTMENT OF HEALTH AND FAMILY SERVICES

MEDICAID 1115 RESEARCH AND DEMONSTRATION WAIVER APPLICATION

A PHARMACEUTICAL BENEFIT FOR LOW-INCOME WISCONSIN SENIORS

March 29, 2002

Wisconsin Department of Health and Family Services
1115 Demonstration Waiver Application

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I. EXECUTIVE SUMMARY

Research has demonstrated that prescription drugs are a necessary and cost-effective method of providing health care. Studies have estimated that every dollar spent on pharmaceutical coverage is associated with a significant reduction in hospital care expenditures. Nevertheless, data indicate that many seniors lack any, or adequate, prescription drug insurance coverage.

In response to the need for drug coverage for the elderly, the State of Wisconsin, in 2001 Wisconsin Act 16, established a prescription drug assistance program called SeniorCare. Act 16 mandates that SeniorCare be implemented no later than September 1, 2002. The legislation provides $49.9 million in state general purpose revenue in state fiscal year 2002-03 to fund the prescription drug benefits covered by SeniorCare for the ten-month period from September 1, 2002 to June 30, 2003. The legislation also requires the Department of Health and Family Services (DHFS) to seek a federal Medicaid demonstration project waiver for SeniorCare prescription drug coverage.

The State of Wisconsin Department of Health and Family Services requests a Section 1115 Demonstration Waiver for its SeniorCare prescription drug program. SeniorCare extends Medicaid eligibility through Title XIX to cover prescription drugs as a necessary primary health care benefit that many seniors lack. The target population for services under this demonstration project includes seniors 65 years of age or older with income below 240% of the federal poverty level (FPL), which is $21,264 for an individual and $28,656 for a two-person family in 2002. Seniors who incur high drug costs may spend down to this income level to receive benefits. There is no asset test. To be eligible, individuals may not be already enrolled in Medicaid, and must pay a $20 enrollment fee. Individuals with income between 160% and 240% of the FPL must pay the first $500 in prescription costs, and all program recipients are required to pay a $5 copayment for generic drugs and a $15 copayment for brand name drugs.

It is projected that providing an enhanced comprehensive pharmacy benefit under the proposed waiver will extend coverage to prescription drugs to approximately 177,000 low-income seniors in Wisconsin.

Additional SeniorCare statutory requirements correspond to existing requirements for Medicaid, including coverage of drugs, pricing, use of certified providers, coordination of benefits with other insurers, rebates, benefits management, and cost containment strategies. In addition, SeniorCare will comply with federal and state Medicaid laws and regulations for eligibility, benefits, and administration.

The Department projects that the waiver expansion will not increase Medicaid expenditures for the aged population, 65 and older, from what would have been expended without the waiver program. This estimate is based on the assumption that providing pharmacy benefits will improve the quality of primary care by preventing catastrophic illnesses requiring institutionalization of people aged 65 and older. As a result, these

individuals will become Medicaid-eligible less quickly. It also assumes that those individuals not necessarily at risk of institutionalization will maintain their own financial resources for a longer period of time, making them eligible for Medicaid benefits less quickly. The savings realized by reducing the rate of increase in non-pharmacy Medicaid services for this population will offset the costs of expanding the pharmacy benefit under this program.

SeniorCare will fill a critical gap in the coverage of necessary primary health care services for low-income seniors. The additional 177,000 Medicaid recipients in the waiver program, which is almost three times the current number of annual Medicaid aged recipients, will provide important data on the utilization, delivery, and cost-effectiveness of prescription drug coverage. Moreover, because SeniorCare more closely resembles a private sector insurance policy, the waiver will provide valuable data regarding program design for other potential pharmacy assistance programs. It is estimated that this federal and state partnership will achieve these goals without increasing either federal or state Medicaid costs. However, an additional and significant benefit of this waiver program not accounted for in the cost-effectiveness analyses, is the reduction in expenditures to be realized by the Medicare Program. Similar to savings to be realized by the Medicaid program, it is anticipated that the Medicare program will achieve significant savings through reduced hospitalizations for this population group.

II. OVERVIEW

A. Prescription Drugs and the Elderly

The lack of prescription drug coverage for seniors under the Medicare program is one of today's most important public policy issues. Although seniors represent approximately 9 percent of the United States population, they account for one-third of all drug expenditures.[1] In addition, many of the elderly's most vulnerable populations including the rural, near-poor and the frail elderly are most likely to lack drug coverage[2]. As people in the United States live longer, the proportion of senior citizens in this country will continue to grow. Drug costs are also on the rise. At the same time, benefits from Social Security and Supplemental Security Income have increased at a much slower pace (only 1.3 percent in 1999).[3] The combination of a larger elderly population and more expensive drugs will become more costly to seniors and the government if state and federal payers of health care, particularly Medicare, do not soon develop an option to provide seniors with comprehensive primary care benefits by extending coverage to prescription drugs.

Drug coverage has been repeatedly linked to health status. Sixty-four percent of Medicare beneficiaries have no supplemental insurance coverage for outpatient drugs. These individuals tend to be more ill than individuals with some type of supplemental insurance. Of those without supplemental drug coverage, 40 percent report that their health is only fair or poor; only 23 percent of those with supplemental drug coverage report a fair or poor health status.[4] Until a national solution to the lack of Medicare coverage can be implemented, through a Medicaid waiver, Wisconsin proposes to partner with the Centers for Medicare and Medicaid Services (CMS) to address this issue.

As health care costs continue to rise for all Americans, access to drugs for this population, a basic primary care benefit, is increasingly important. The lack of access to essential medications for the chronically ill and those with acute diseases result in an increase in hospital and nursing home costs. Use of prescription drugs not only improves the quality of primary care services, but is also cost-effective when including the cost of hospitalization or long-term care. Studies have estimated that every dollar spent on pharmaceutical coverage is associated with a significant reduction in hospital expenditures.[5] These savings relate not only to the preventive nature of some pharmaceuticals, but also to the fact that inadequate coverage of this primary care benefit causes millions of low-income elderly to reduce their use of clinically essential medications. The improper use of essential medications due to income constraints increases hospital and nursing home admissions, increasing health care costs in the aggregate.[6]

Currently, many seniors' primary care benefits are limited because Medicare excludes prescription drug coverage, an integral part of comprehensive primary care. This lack

of access to prescription drugs for the elderly is one of the most significant issues confronting our national health care system.

B. Current Elderly and Disabled Wisconsin Medicaid Eligibility

1. Supplemental Security Income (SSI)

Wisconsin provides Medicaid coverage to all persons who receive federally funded cash assistance under the Supplemental Security Income (SSI) program. Wisconsin is not a "section 209(b) state" and, thus, does not impose more restrictive eligibility standards than SSI.

Within the population of SSI-eligible elderly and disabled persons, the federally mandated coverage group is persons who qualify for and receive the federal SSI payment. Wisconsin has chosen to cover the additional optional groups of persons who receive a state-only supplemental payment, as well as persons who are eligible for the federal SSI payment, but choose not to receive it. In calendar year 2002, elderly and disabled persons with income below $628.78 per month for an individual and $949.05 for a couple, could be eligible for Medicaid in Wisconsin.

Wisconsin meets federal requirements with regard to a number of groups of persons formerly eligible for SSI. The state covers certain disabled persons who have returned to work and lost SSI eligibility as a result of employment earnings, but still have the condition that rendered them disabled (and meet all non-disability criteria for SSI except income). Also covered are persons once eligible for both SSI and Social Security payments who lost their SSI because of certain cost of living adjustments to their Social Security. Similar Medicaid continuations are provided for certain other persons who become ineligible for SSI due to eligibility for, or increases in, Social Security or veterans' benefits. Wisconsin also maintains Medicaid coverage for certain SSI-related groups who received benefits in 1973, including persons who care for disabled individuals.

2. Medically Needy

Wisconsin also offers Medicaid coverage to medically needy elderly and disabled persons. By federal law, the associated income standards may not exceed 133.3% of the maximum AFDC payment that would have been paid to a family as of July 16, 1996. Wisconsin exercises the federal option to apply the higher two-person standard to single individuals. Further, Wisconsin has opted to provide nursing home care as part of its medically needy program benefit package.

Medical costs are covered under Wisconsin's medically needy Medicaid program when the person (or family) depletes assets to a certain level ($2,000 for an

individual, $3,000 for a couple) and spends any excess income (i.e., income over the medically needy limit) for medical expenses.

3. Institutional and Other Long-Term Care

Wisconsin provides Medicaid coverage to nursing home residents and persons participating in community-based long-term care programs under a special optional institutional income rule. This rule permits persons who are not categorically eligible for SSI and who have income between 100% and 300% of the monthly federal SSI payment amount, to be eligible for Medicaid without "spending down" to the medically needy income limit. Wisconsin has opted to provide coverage at the maximum of 300% of the monthly SSI payment level.

4. Medicaid Purchase Plan

In March of 2000, Wisconsin implemented a new option provided under federal Medicaid law, extending Medicaid coverage to certain working, disabled adults. The program is intended to remove financial disincentives to work and generally covers disabled individuals with income under 250% of the federal poverty level. Disability and family income are determined in accordance with SSI rules and there is a $15,000 asset limit. Program participants must engage in gainful employment, or participate in a program certified to provide health and employment services aimed at helping the individual achieve employment goals.

5. Low-Income Medicare Beneficiaries

Wisconsin provides limited Medicaid coverage to the following groups of low-income Medicare beneficiaries:

- Qualified Medicare Beneficiaries (QMB): These are persons entitled to Medicare hospital insurance benefits (i.e., Medicare Part A) whose income does not exceed 100% of the federal poverty level and whose resources do not exceed twice the Supplemental Security Income (SSI) resource limit. For such persons, Medicaid reimburses any required Medicare premium, coinsurance and deductibles for both Parts A and B. Cost sharing amounts are paid up to the maximum amount Medicaid would reimburse for the service rendered.

- Specified Low-Income Medicare Beneficiaries (SLMB): Medicaid pays the full Part B premium for persons who otherwise meet the QMB requirements, but have income between 100% and 135% of the federal poverty level.

- Additional Low-Income Medicare Beneficiaries (ALMB): Medicaid pays a portion of the Part B premium for persons who otherwise meet the QMB

requirements, but have income between 135% and 175% of the federal poverty level.

- Qualified Disabled and Working Individuals (QDWI): These are persons who formerly received social security disability benefits and Medicare, have lost eligibility for both programs, but are permitted under Medicare law to continue to receive Medicare in return for payment of the Part A premium. Wisconsin has chosen to pay the entire Part A premium for persons in this category who are under age 65, with income at or below 200% of the federal poverty level and with assets up to twice the SSI resource limits (and who are not otherwise Medicaid eligible).

C. Overview of Demonstration Waiver Program (SeniorCare)

In response to the critical need for prescription drug coverage for the elderly, the State of Wisconsin, as part of 2001Wisconsin Act 16, established a prescription drug assistance program titled SeniorCare. The legislation allocated $49.9 million in state general purpose revenue in state fiscal year 2002-03, the first year of the program, to fund prescription drug benefits covered by SeniorCare for the ten-month period beginning on the legislatively mandated start date of September 1, 2002 to June 30, 2003.

SeniorCare statutes also require the Department of Health and Family Services to submit to the U.S. Department of Health and Human Services the request that SeniorCare be covered under a Medicaid 1115 Demonstration Waiver program. Accordingly, many of the statutory requirements for SeniorCare correspond to existing requirements for Medicaid, including coverage of legend drugs, pricing, automated transmission of reimbursement rates, use of certified providers, coordination of benefits with other insurers, benefit management and cost containment strategies, and manufacturer rebates. In addition, SeniorCare will comply with federal and state laws and regulations (except those for which a specific waiver is requested) for Medicaid eligibility, benefits, and administration, including application processing, claims processing, federal reporting, and safeguards for fraud and abuse.

The State of Wisconsin Department of Health and Family Services (the Department), the agency that administers the state's Medicaid program, will also administer SeniorCare. SeniorCare provides a comprehensive pharmacy benefit to Wisconsin residents 65 years of age and older whose income is at or below 240 % of the federal poverty level (FPL). Seniors who incur high drug costs may spend down to 240% of the FPL to receive benefits. Through a Section 1115 Research and Demonstration waiver, the state seeks Medicaid federal matching funds for individuals who qualify for SeniorCare pharmacy benefits. As a result of the expanded pharmacy benefit, the number of participants in the program will significantly increase. It is anticipated that this proposal will provide increased access to more comprehensive primary health

care services by extending coverage to pharmaceuticals for approximately 177,000 Wisconsin seniors.

By expanding access to prescription drugs for the elderly, Wisconsin intends to provide a needed health care benefit to low-income seniors. The Department proposes to demonstrate that providing pharmacy benefits to an expanded population will provide the following benefits:

- Help to preserve the health of the senior population by providing financial support for costly but essential drugs, thereby providing more comprehensive primary health care services.

- Improve the quality of life of Wisconsin's seniors, thus allowing them to remain in less costly home and community settings while avoiding expensive acute or long-term care services resulting from a lack of access to necessary drugs.

- Reduce the rate at which seniors "spend down" to Medicaid eligibility and become entitled to all benefits available under the Medicaid program.

- Reduce Medicaid expenditures for the dual-eligible population.

- Save the federal government money by improving the health of seniors, resulting in savings to the Medicare program.

Under the program, Wisconsin residents who are 65 years of age and older, not currently eligible for Medicaid benefits, and whose income does not exceed 240% of the federal poverty level (FPL), are eligible for coverage for legend drugs as currently provide under the Wisconsin Medicaid State Plan. Seniors with income in excess of 240% of the FPL are also eligible to enroll in SeniorCare but will have a spend-down requirement. Those seniors with prescription drug coverage under other plans are also eligible to enroll, with SeniorCare covering eligible costs not covered under other plans. There will be no asset test for eligibility.

Enrollees will pay an annual $20 enrollment fee. Individuals with income at or below 160% of the FPL are responsible for a copayment, of $15 for a brand name drug and $5 for a generic drug, for each prescription drug. Individuals with income above 160% of the FPL also will be responsible for the first $500 of prescription drug costs each year. Participants with income above 240% of the FPL are responsible for the first $500 of prescription drug costs per year after they have spent down by purchasing prescription drugs to the eligible income level.

It is estimated that 325,000 Wisconsin residents will be eligible, on the basis of income, for SeniorCare. It is projected that approximately 177,000 individuals will enroll in the program with approximately 120,600 enrollees at or below 160% of the,

38,700 enrollees between 160% and 240% of the FPL, and 17,100 enrollees over 240% of the FPL (spend-down eligible).

The application form, a simple one-page form that will be available in the summer of 2002, will request the applicant's name, age, social security number, income, residence, spouse's name and other limited information needed to determine the person's eligibility. The form will be easy to read and complete. Seniors will submit applications by mail to a central processing center administered by the Department.

Customer notices will inform seniors about their eligibility, whether they have a spenddown and/or annual payment, the amount of the spenddown and/or annual payment, and other information regarding their participation in the program. Upon enrollment, waiver program recipients will receive an identification card, distinct from the normal Medicaid card, which enrollees will use when purchasing prescription drugs. Enrollees will be certified to begin participation in the program on the first day of the month following the month in which all eligibility criteria are met. Once determined eligible for the waiver program, an individual may remain eligible for 12 months from the date of initial enrollment, regardless of changes in income.

SeniorCare will use the state Medicaid program's Point-of-Sale (POS) system for claims processing. The POS system has in place the mechanisms for drug pricing, calculation of copayments and deductibles, providing enhanced pharmaceutical care services, STAT prior authorization, prospective and retrospective Drug Utilization Review (DUR), and other cost containment processes. The system enables Medicaid-certified providers to submit real-time claims electronically for prescription drugs and to receive an electronic response indicating payment or denial within seconds of submitting the claim. The system also verifies recipient eligibility, including other health insurance coverage, and will track participants' spenddown, deductibles and copayments, again with the information available to pharmacists in real-time. As a result, seniors filling their prescriptions may receive up-to-date information about their prescription costs.

Similar to Medicaid, SeniorCare must coordinate eligibility across programs and coordinate with benefits covered by other insurers. Many seniors who are eligible for SeniorCare will also be eligible for programs such as food stamps or other economic support programs. A SeniorCare customer service hotline will be operational in July 2002 to respond to questions about eligibility, applications and program benefits. SeniorCare application processing staff will be trained to answer questions and provide referrals for seniors seeking information about SeniorCare or other programs.

Existing systems that support the Medicaid program will be used for automated support for eligibility and enrollment functions. The state will leverage existing system capacity, to meet the program needs in the most efficient way, and prepare for the implementation of SeniorCare as a Medicaid benefit program. A comparable

result was successfully achieved for low-income families with children in the state's Title XXI demonstration waiver, BadgerCare, which provided seamless coordination with Medicaid, including elimination of the welfare stigma of Medicaid-funded services through program design, public information, and cost sharing.

SeniorCare will fill a critical gap in necessary primary health care coverage available to low-income seniors. The addition of the projected 177,000 program enrollees to the Medicaid waiver program also will provide important data on the utilization, delivery, and cost-effectiveness of prescription drug programs for the elderly. Moreover, it is estimated that this federal and state partnership will achieve these goals without increasing either federal or state costs from what would have resulted without the program. A more detailed analysis of the projected expenditures and savings associated with the waiver program is provided later in this report.

III. PROPOSED DEMONSTRATION WAIVER PROGRAM DESIGN

A. Eligibility Requirements

State Medicaid programs may have two types of eligibility categories: categorically needy and medically needy. Both categories are established under the Social Security Act. Certain groups, such as pregnant women or the elderly, are considered categorically eligible if they also meet income criteria based on the FPL. "Medically needy" eligibles are those that would be categorically needy except for their slightly higher income, but who cannot afford to pay their medical bills. To be eligible for prescription drug services under this 1115 Research and Demonstration waiver program, individuals must:

- Be a Wisconsin resident;
- Not be a recipient of Medicaid other than as a low-income Medicare beneficiary;
- Be age 65 or older; and
- Pay the applicable annual enrollment fee of $20 per person.

Individuals must also have a household income at or below 240% of the FPL. Individuals with a household income above 240% of the FPL will also receive program benefits after they have incurred sufficient costs for prescription drugs to spend down to 240% of the FPL. Income will be calculated as follows:

- A gross income test will be used, except in cases of self-employment income. The standard elderly, blind and disabled (EBD) Medicaid deductions or other deductions will not be applied.

- In cases of self-employment income, current Medicaid policy for elderly, blind and disabled programs will be followed. Therefore, deductions for business expenses, losses and depreciation will be permitted for persons with self-employment income.
- Income will be determined annually, on a prospective basis.
- A fiscal test group that is consistent with current Medicaid policy for elderly, blind and disabled program will be used. Thus, the income of the individual will be used for persons not living with a spouse, and the income of the couple will be used for married persons who reside with their spouse. These income amounts will be compared to the FPL for a group size one if counting only the income of the individual and group size two if counting the income of the applicant and his or her spouse.
- There will be no asset test related to eligibility for the waiver program**.**

B. Application Process for Pharmacy Waiver Benefits

The application process for eligibles in this 1115 Research and Demonstration waiver program will be comprised of the following components:

- A separate application will be developed for the waiver program; this application will be for the waiver program only.

- A central unit administered by the Department will process applications.

- Applications will be accepted by mail. In the future, the Department may accept applications by telephone, electronically, over the Internet or by other means, as appropriate, as determined by the Department.

- Near the end of an individual's year of eligibility, the Department will notify the recipient of the need for an annual re-determination of his or her eligibility. The Department will provide the individual with forms for the redetermination of eligibility. To continue coverage, the form must be filed in a timely manner and receive approval. The individual must also pay the annual enrollment fee.

- Upon enrollment, SeniorCare waiver program participants will receive an identification card distinct from the current Medicaid card. Participants must present the identification card to the pharmacy or pharmacist when purchasing prescription drugs.

- The application process will focus primarily on eligibility for the SeniorCare Medicaid waiver program. In addition, applicants will be advised to complete a full Medicaid application if they are applying for benefits other than prescription drugs.

C. Enrollment Periods

Enrollment periods for eligibles will be as follows:

- Once determined eligible for the SeniorCare waiver program, an individual may remain eligible for 12 months from the date of initial enrollment, regardless of changes in income. However, if a person permanently leaves the State of Wisconsin or becomes deceased, the person is no longer eligible for the waiver program.

- Participants may reapply if their income decreases. For example, if a person with an income determination of 165% of the FPL subsequently loses a part-time job resulting in income below 160% of the FPL, the individual may reapply. In this situation, the person would no longer be required to pay the first $500 in prescription drug costs, but would need to pay a new $20 enrollment fee to establish a new 12-month benefit period.

- A person will be certified to begin participation in the program on the first day of the month following the month in which all eligibility criteria are met.

- Eligibility for benefits will be prospective only; there will be no retroactive eligibility.

D. Coordination of Benefits

The waiver program pharmacy benefit will extend coverage only to legend drugs and to insulin, drugs that are currently covered by the Wisconsin Medicaid State Plan. This pharmacy benefit will inherently enhance and complement primary health care benefits for this waiver population. Coordination of benefits will be applied in a manner similar to the Medicaid Program. The SeniorCare Program will use a combination of automated, pre-payment cost avoidance with the Point-of-Sale (POS) system and, where necessary, will pay and chase to coordinate benefits with liable third parties. Proposed statutory changes will also allow the Department to collect insurance information for SeniorCare recipients from insurers through the current insurance disclosure process.

E. Cost Sharing

Participants in the program will be required to comply with cost sharing provisions that vary by income level. The following describes these provisions in more detail.

1. Annual Enrollment Fees

All participants will be required to pay an annual enrollment fee of $20. Upon determining eligibility, all enrollees will receive a letter notifying them of their

eligibility and cost-sharing requirements. All enrollees will receive the option to decline participation if the person notifies the Department within the 30-day processing period, or 10 days from the date the Department sends the letter, whichever is later. If a person declines participation within this time period, the Department will refund the enrollment fee paid for that benefit period. If a person has paid the annual enrollment fee with his or her application and is determined ineligible for the program, the Department will refund the paid enrollment fee.

2. Annual Costs For Certain Participants

Certain participants will pay the first $500 in prescription drug costs each enrollment period, similar in effect to a premium payment.

- Participants with income above 240% of the FPL are responsible for the first $500 of prescription drug costs per year after they have spent down by purchasing prescription drugs to the eligible level.
- Participants with income between 160% of the FPL and 240% of the FPL are responsible for the first $500 of prescription drug costs per year.
- Participants with income at or below 160% of the FPL are not required to pay the first $500 of prescription drug costs.

3. Copayments

For participants with income above 160% of the FPL who have met the $500 annual payment, and for participants with income below 160% of the FPL, a copayment is required for each prescription drug for the remainder of that 12-month period. The following copayments apply:

- Participants are required to pay a $15 copayment per prescription for brand name drugs.
- Participants are required to pay a $5 copayment per prescription for generic drugs.

F. Coordination with Other Medicaid Programs

The following are stipulations regarding coordination between the Medicaid program and the 1115 Research and Demonstration waiver program:

- A participant whose income decreases to allowable Medicaid eligibility levels must submit a complete Medicaid application and be determined eligible through existing procedures to receive full Medicaid benefits.

- Except for the 30-day initial processing period, the enrollment fee is not refundable to participants in the waiver demonstration project who, during their 12-month benefit period, become eligible for full Medicaid benefits. However, SeniorCare will remain open to these individuals. Thus, if they subsequently become ineligible for full Medicaid benefits during the 12 months, they will automatically be able to receive SeniorCare benefits again without have to re-apply or pay another $20 fee.

- Participants who are terminated from the SeniorCare waiver program or who fail to re-enroll will not be reviewed for eligibility for other Medicaid programs prior to termination.

G. Benefits, Rates and Cost Management Strategies

1. **Benefits.** Wisconsin Medicaid covers legend (prescription) drugs prescribed by a licensed physician, dentist, podiatrist, nurse prescriber, or optometrist. In addition, physicians may delegate prescription authority to a nurse practitioner or physician assistant.

   Wisconsin Medicaid has an open drug formulary. This means that legend drugs are covered if they meet all of the following criteria:

   - The drug is FDA-approved;
   - The manufacturer signed a rebate agreement with the Health Care Financing Administration (now Centers for Medicare & Medicaid Services); and
   - The manufacturer has reported data and prices to First DataBank.

   SeniorCare statutes define prescription drugs as prescription drugs covered by Wisconsin Medicaid and for which the drug manufacturers enter into a rebate agreement with the State. However, like Wisconsin Medicaid, which covers certain over-the-counter drugs, SeniorCare may extend coverage to insulin.

2. **Rates.** Medicaid reimbursement for legend drugs is the lesser of:

   - Average wholesale price (AWP) less 11.25%, plus a dispensing fee, for most brand drugs;
   - The maximum allowed cost (MAC), plus a dispensing fee, for multi-sourced branded and generic drugs; or
   - The usual and customary amount as billed by the pharmacy to private pay clients.

   SeniorCare payment rates are set in statute at the Medicaid rate plus 5 percent, plus a dispensing fee equal to the Medicaid dispensing fee. The allowed amounts are approximately 20 percent less than standard retail rates. However, "spend-down"

individuals will pay the retail rate charged by the pharmacy until they meet the income limit of 240 % of the FPL.

SeniorCare legislation requires automated transmission of rates to providers. Pharmacies are prohibited from charging enrollees an amount that exceeds the allowed amounts set in statute.

3. **Cost Management Strategies**. To further enhance the primary health care benefits and the cost-effectiveness of the SeniorCare waiver program, the Department plans to implement a number of management strategies to enhance the quality of care and cost-effectiveness within the waiver program. These benefit management strategies, which are currently used in the State Medicaid program, would be extended to SeniorCare and include the following:

   a. Pharmacy Point-of-Sale (POS)

   Wisconsin Medicaid implemented a pharmacy point-of-sale electronic claims management system for Medicaid fee-for-service providers statewide beginning September 22, 1999. The POS system enables providers to submit real-time claims electronically for legend and over-the-counter drugs for immediate adjudication and eligibility verification. The real-time claims submission verifies recipient eligibility, including other health insurance coverage, and monitors Medicaid drug policies. Claims are also screened against recipient medical and prescription history within the Medicaid system. Once these processes are complete, the provider receives electronic response indicating payment or denial within seconds of submitting the real-time claim.

   The following have occurred since the implementation of POS:

   - POS permits pharmacies to submit claims and receive notification of coverage before drugs are dispensed.

   - Currently, most of the state's 1200 pharmacies are participating in real-time transactions. As many as 30,000 real-time Medicaid transactions are processed every day.

   - The average system response time is 0.4 seconds. Of all drug claims received by Medicaid, 90% to 95% are submitted real-time.

   - Claims with "other health insurance" listed must be billed to that other insurance first.

- Wisconsin continues to be one of the few states in the country that denies claims up front if records indicate the recipient has other health insurance that pays for drugs.

- Claims for the same drug on the same day by one recipient at different pharmacies are denied because claims history is updated real-time and all Medicaid pharmacy claims are reviewed.

b. Prospective Drug Utilization Review

Prospective Drug Utilization Review (DUR) is used to enhance clinical quality and cost-effective drug use by participants. At the point of sale, the Medicaid POS system screens certain drug therapy problems before the prescription is dispensed to the recipient. The screen provides the pharmacist with information regarding potential contraindications for the recipient by activating alerts that identify the following problems, which are presented in hierarchical order:

- Drug-drug interactions

- Drug-disease contraindications

- Therapeutic duplication

- Pregnancy alert

- Early refill

- Additive toxicity

- Drug-age precaution

- Late refill

c. Retrospective Drug Utilization Review

The Department on a monthly basis will perform retrospective DUR review. Review of drug claims against DUR Board-approved criteria generate patient profiles that are individually reviewed for clinical significance. Each month a software program for potential adverse drug concerns such as drug/drug interactions, overuse, drug/disease contraindications, duplicate therapy, and high dose will be examined for all providers. If a potential drug problem is discovered, intervention letters are sent to all providers who ordered a drug relevant to the identified problem.

d. Maximum Allowed Cost (MAC) List

The federal Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) issues a drug list at least two times a year. This list includes drugs that are available generically from at least three companies as well as a recommended maximum allowed cost (MAC). In addition, states may have their own MAC lists and set prices differently from the CMS issued prices as long as the overall amount spent for generic drugs is no more than it would have been using the CMS prices.

Wisconsin Medicaid issues its MAC list quarterly and has one of the most extensive MAC lists in the country. SeniorCare will also use the Wisconsin Medicaid MAC list. If a product is available generically Wisconsin Medicaid generally adds it to the state's MAC list. Maximum prices allowed are based on prices for which drugs are readily available through wholesalers in Wisconsin. When a drug is on the MAC list, Wisconsin will only reimburse the generic price unless the prescriber writes "brand medically necessary" on the prescription. Less than 2% of Wisconsin Medicaid prescriptions currently indicate that the brand is medically necessary. In addition, because Wisconsin's MAC list is more extensive than the CMS list, the savings to the state are considerably higher than they would be using the CMS list alone.

e. Pharmaceutical Care

Wisconsin's Medicaid's Pharmaceutical Care (PC) program provides pharmacists with an enhanced dispensing fee for PC services provided to Wisconsin Medicaid recipients. The enhanced fee reimburses pharmacists for additional actions they take beyond the required dispensing and counseling for a prescription drug. A PC profile must be created and maintained for the recipient prior to submitting a PC claim. It must include the intended use or diagnosis information for each drug that the recipient is actively using.

Reimbursement for the PC dispensing fee requires that pharmacists meet all basic requirements of federal and state law for dispensing a drug plus completion of specified activities that result in a positive outcome both for the recipient and the Medicaid program. Positive outcomes include increased patient compliance and prevention of potential adverse drug reactions.

f. Prior Authorization

Under prior authorization (PA), Wisconsin Medicaid requires pharmacists to receive approval for certain drugs from the Department before reimbursement is provided. PA may be done electronically for most drugs requiring PA. Wisconsin requires drug prior authorization for the following reasons:

- Potential drug abuse or misuse
- Cosmetic use only (for example, weight loss drugs not used to treat morbid obesity)
- Encourage use of therapeutically equivalent drugs when generics are available in the same drug classification. This is also known as targeted PA.

While less than 1% of covered drugs require PA, targeted PA has been shown to slow the rate of increase in drug expenditures without impeding access to necessary and appropriate drugs. Through PA, categories of drugs are reviewed for similar products, some of which are available generically and some only brand. When this situation exists, Wisconsin may recommend requiring PA for the brand drugs. However, before any changes are made to the PA requirements, drug manufacturers are notified and a review process is followed. This process assures high quality to our recipients and cost-effectiveness for the program.

g. Diagnosis Restriction and Excluded Drugs

Under Wisconsin Medicaid, a diagnosis restriction applies if the prescribed use is not for a medically accepted indication. In addition, certain drugs may be excluded from coverage and are on the Medicaid Negative Formulary drug list, including drugs that are less-than-effective as defined by the Food and Drug Administration (FDA), and drugs that are experimental or have no medically accepted indications.

IV. WAIVER PROGRAM IMPLEMENTATION AND ADMINISTRATION

A. Administering Agency

The State of Wisconsin will administer the waiver program through the Wisconsin Department of Health and Family Services. Portions of the program may be administered by private entities under contract with the State. The waiver program will use the Wisconsin Medicaid fiscal agent, Electronic Data Systems (EDS), to provide health claims processing, communications, customer service, application processing and other related services. The Medicaid eligibility agent, Deloitte

Consulting, will provide the system capabilities for conducting eligibility determinations.

B. Financing

Prescription drug services under the 1115 Research and Demonstration waiver program will be funded jointly through State general purpose revenue (GPR) funds and matching federal funds. Additional program revenue for the 1115 Research and Demonstration waiver program will come from the previously mentioned, annual enrollment fees, copayments, and monies from the drug rebate program. Wisconsin currently has drug rebate agreements with all pharmaceutical companies participating in the Medicaid rebate program pursuant to Section 1927 of the Social Security Act. This program will continue to rely on rebate agreements in future periods.

C. Provider Network

Pharmacies currently enrolled in the Wisconsin Medicaid program will fill prescriptions for waiver program participants as well. Access to pharmacies for the waiver program will be readily available as approximately 98% of licensed pharmacies in Wisconsin participate in the Wisconsin Medicaid program.

D. Implementation Schedule

The Department expects the waiver program to last for five years and is aggressively seeking an implementation date of September 1, 2002. Since many of the program design features, including the State Medicaid Point of Sale (POS) system, are already in place the Department is confident that the waiver program will be operational by the target date.

E. Early Termination of the Waiver Program

Wisconsin reserves the right to end this 1115 Demonstration Waiver should actual experience show that it is not cost-effective or cost-neutral. Further, Wisconsin may amend or terminate this program should a federal program provide access to prescription drugs for all or part of the waiver population. Wisconsin residents will not be disadvantaged with regard to their participation in any such federal program as a result of the state's decision to terminate this waiver program. Wisconsin may also choose to seek a Medicare waiver for the State in order to coordinate the programs.

IX. WAIVERS REQUESTED

This demonstration program requires waivers from Title XIX of the Social Security Act. Section 1115(a)(1) of the Social Security Act permits the Secretary of the Department of Health and Human Services (the Secretary) to waive compliance with any of the requirements of Section 1902 of the Social Security Act, which specify State Medicaid

Plan requirements, to the extent and for the period necessary to carry out the demonstration project. Section 1115(a)(2) permits Wisconsin to regard as expenditures under the State plan costs of the demonstration project, which would not otherwise receive a federal match under section 1903 of the Social Security Act. These provisions allow the Secretary to waive existing program restrictions and provide expanded eligibility and/or services to participants not otherwise covered by Medicaid. Wisconsin requests that the Secretary waive all relevant Medicaid laws and regulations which would allow Wisconsin to receive federal matching funds, including the following Title XIX provisions:

A. Eligibility. Wisconsin requests the Secretary to waive Sections 1902(a)(10)(A) and 1902(a)(17) of the Social Security Act. These sections prohibit Federal Financial Participation to states that implement eligibility standards in excess of the stated maximums and in manners not consistent with the standards prescribed by the Secretary. These sections also specify that methodologies must be applied in the same manner to all individuals in the same eligibility group. Wisconsin seeks a waiver to:

- Expand eligibility for pharmaceuticals to waiver demonstration participants with incomes at or below 240 percent of the federal poverty guideline, and to individuals with incomes above 240 percent of the federal poverty guideline who, after becoming eligible, would be required to spend down to receive program benefits (as noted earlier, there will be no asset test for eligibility under the waiver demonstration);
- Apply different methodologies as described above to waiver demonstration participants than would be applied to blind and disabled persons under age 65 or to regular Medicaid recipients.
- Apply different standards than those prescribed by the Secretary related to eligibility determination. Eligibility will be redetermined and income will be reassessed for waiver participants once every 12 months.

B. Comparability. Wisconsin requests the Secretary to waive Section 1902(a)(10)(B) of the Social Security Act. These sections require the amount, duration, and scope of services be equally available to all participants within an eligibility category and be equally available to categorically eligible and medically needy participants. Wisconsin seeks a waiver of these provisions to offer a comprehensive drug benefit to the expanded population.

C. Cost Sharing. Wisconsin requests the Secretary to waive Section 1902(a)(14) of the Social Security Act relating to enrollment fees, copayments and other cost sharing. Wisconsin seeks a waiver to:

- Collect an annual enrollment fee of $20 per person. This cost-sharing revenue will be used as state matching funds to federal financial participation for the administrative costs of the program;
- Establish that certain participants in the waiver demonstration would pay the first $500 of prescription drug costs prior to receiving the benefit of obtaining prescription drugs at the copayment levels; and
- Establish copayment amounts higher than those used for the general Medicaid population.

D. Ex Parte Eligibility Redeterminations. Wisconsin requests the Secretary to waive section 1902(a)(19) of the Social Security Act and federal regulations at 42 CFR 435.902 and 42 CFR 435.916 related to *ex parte* eligibility redeterminations. Wisconsin seeks a waiver to:

- Require that a separate waiver demonstration application be filed by an applicant who is no longer eligible for regular Medicaid prior to being determined eligible for the waiver demonstration program; and
- Require a waiver demonstration participant to file a separate Medicaid application if they are interested in receiving benefits under any other Medicaid subprogram.

E. Program Integrity. Wisconsin requests the Secretary to waive Section 1902(a)(46) of the Social Security Act and federal regulations at 42 CFR 435.920 and 42 CFR 435.940 through 435.965 related to verification of applicant and recipient income and eligibility information. It is anticipated that certain income sources may have limited applicability for the waiver demonstration population, which generally is perceived as having fixed income. Further, because income is tested prospectively on an annual basis under the waiver demonstration and because data from other sources represents a prior time period, some items may not be relevant in determining eligibility for SeniorCare. In exploring the most efficient and effective methods for ensuring program integrity, Wisconsin intends to do the following:

- Validate social security numbers at the time of application through the Social Security Administration numident process. If it is found that a person does not have a social security number, the person will be assisted in obtaining a social security number. If it is found that there is a mismatch between the SSA information and the social security number provided by the client, the mismatch will be resolved as needed.
- Automatically test Social Security Administration benefits against tolerance levels established by the Department at application and review. Those case situations that exceed tolerance levels will be verified and discrepancies will be resolved. In addition, periodic random samples of all cases will be conducted to ensure that SeniorCare eligibility is based upon the correct social security benefit information regardless of whether there is a discrepancy that exceeds the threshold.

- In addition, social security administration benefits, earnings from wages, earnings from self-employment, other unearned income and unemployment compensation will be verified after application to ensure program integrity. In particular, a random sample of all recipients will be taken. If a failure to report information results in an incorrect eligibility determination, program costs would be recovered.

F. Spend-down. Wisconsin requests the Secretary to waive Sections 1903(f)(2)(A), 1903 (f)(2)(B) and 1902(a)(17) of the Social Security Act related to spending down income by disregarding certain medical expenses from income in determining eligibility for Medicaid, allowing participants to pay an amount that would effectively lower the family's income prior to incurring medical costs ("pre-payment of the Medicaid spend-down), and application of these procedures in a comparable manner for all groups. Under this waiver demonstration, after becoming eligible for the program, participants with income above 240 percent of the federal poverty guideline will be required to meet a spend-down requirement equal to the amount that is the difference between their income and 240 percent of the federal poverty guideline prior to receiving program benefits within the 12 month enrollment period. Costs incurred only for prescription drugs could count toward the spend-down requirement. Pharmaceutical costs incurred prior to the person being enrolled in the demonstration waiver program would not count toward the spend-down requirement even if paid for after the benefit period begins. Only prescription drug costs that are incurred and paid for during the 12-month benefit period could count toward the spend-down requirement. Thus, a person could not pre-pay the spend-down amount. The treatment of the spend-down provision in this manner would not be consistent with provisions that apply to SSI-related Medicaid recipients.

G. Retrospective benefits. Wisconsin requests the Secretary to waive Section 1902(a)(34) of the Social Security Act and 42 CFR 435.914 that require a state to retrospectively provide medical assistance for three months prior to the date of application in certain circumstances. Wisconsin requests a waiver to establish the effective date for demonstration participants as the date of enrollment as determined in accordance with Section III(C), above.

H. Prescription Drug Rebates. Wisconsin requests the Secretary to waive Section 1902(a)(54) related to prescription drug rebates. Under the waiver demonstration, Wisconsin will enter into rebate agreements with manufacturers. These rebate agreements will allow the state to collect rebate payments for each prescription drug of the manufacturer that is prescribed for and purchased by program participants who have income under 240% of the FPL, or who have income above 240% of the FPL and have met the spend-down requirement. Waiving this section will allow Wisconsin to charge and collect rebates during the period in which the SeniorCare participant pays the first $500 of prescription costs for drugs at the allowed SeniorCare payment rates, as required by state law.

I. Enrollment. Wisconsin requests the Secretary to waive Section 1902(a)(10) of the Social Security Act related to entitlement of benefits. Wisconsin statutes require that, during any period in which funding for benefit payments under the program is completely expended, all of the following shall apply:

- The Department may not pay pharmacies or pharmacists for prescription drugs sold to program participants;
- Pharmacies and pharmacists will not be required to sell drugs to eligible program participants at the program payment rate;
- Eligible program participants will not be entitled to obtain prescription drugs for the copayment amounts or at the program payment rate;
- The Department may not collect rebates from manufacturers for prescription drugs purchased by program participants; and
- The Department is required to continue to accept applications and determine eligibility for the program, and must indicate to applicants that the eligibility of program participants to purchase prescription drugs under the requirements of program is conditioned on the availability of funding.

J. Hearings and Appeals. Wisconsin requests the Secretary to waive Section 1902(a)(3) of the Social Security Act and federal regulations at 42 CFR 431.211 and 42 CFR 431.213 relating to required notification by the Department prior to an adverse action in cases where the recipient has clearly indicated that he or she no longer wishes to receive services. These sections specify that the 10-day required notification prior to an adverse action does not apply in cases where the recipient has clearly indicated *in writing* that he or she no longer wishes to receive services. Under the waiver demonstration, an exception to the 10-day required notification would apply in cases where the recipient has clearly notified the Department *either orally or in writing* that he or she no longer wishes to receive services.

In addition, Wisconsin requests that, under the authority of Section 1115(a)(2), expenditures for the items identified below (which are not otherwise included as expenditures under Section 1903) be regarded as expenditures under Wisconsin's Medicaid State Plan:

- Expenditures to provide and receive comprehensive pharmacy benefits to seniors age 65 and older whose income is at or below 240 % of the FPL or those seniors with income above 240% of the FPL who spend down to become eligible for the program.
- Administrative expenditures for demonstration participants includes, but is not limited to, collecting program participants' fees, enrolling pharmacies, producing and distributing enrollment cards to program participants, responding to client inquires, developing and processing applications, determining eligibility, collecting third-party insurance information and evaluation and monitoring of this demonstration waiver.

Wisconsin requests the right to request other waivers to implement the proposed pharmacy program, if necessary.

V. BUDGET AND COST-EFFECTIVENESS ANALYSIS

Research shows that appropriate and necessary use of pharmaceuticals improves the health of seniors. Studies have shown that providing prescription drugs to those that cannot afford them, results in improved drug-regiment adherence and clinical outcomes as well as significant reductions in hospitalizations. Studies have estimated that every dollar spent on pharmaceutical coverage is associated with a $2.10 to $4.00 reduction in health care expenditures.[7,8,9] In the Medicare program, spending more on prescription drug coverage has the potential to save the Medicare trust funds a significant amount in coverage areas, such as hospitalizations. In the Medicaid program, savings may occur as a result of a decrease in the use of hospital, long-term care and other related medical services.

Findings released in 1991 show that a New Hampshire policy limiting the number of prescription drugs to seniors resulted in significant cost increases to its Medicaid program.[10] Although the cost the state paid for pharmaceuticals dropped 35 percent almost one year after the implementation of the limitation, admissions to nursing homes increased by 60 percent. In addition, the state experienced an increase in the number of hospital stays, visits to community mental health centers and emergency mental health services.[11, 12] After the pharmacy limitation was repealed, total health care costs dropped and admissions to nursing homes returned to their previous level.[13]

Despite the fact that pharmaceutical drugs may be a key component or the only treatment for an illness, the absence of pharmaceutical-insurance coverage causes millions of low-income elderly to reduce their use of clinically essential medications. The lack of essential medications increases hospital and nursing home admissions, decreases the quality of primary care and results in increased health care system costs in the aggregate.[14].

For most people, having to make a decision to purchase food or essential medication is not a common occurrence. But for those elderly who do not qualify for state Medicaid programs and who cannot afford to purchase private insurance for prescription drugs, choosing between food and prescription drugs may not be unusual. Data released in 1999 in the *New England Journal of Medicine* showed that:

"*…among Medicare beneficiaries with incomes less than $10,000 [excluding Medicaid eligibles], almost two-thirds have no drug coverage and purchase only half as much medications as those with employer coverage despite being sicker."* [15]

It is difficult to quantify the elasticity of demand for prescription drugs. However, this research implies that as money becomes tighter, people must choose between the immediate needs of food and housing and the more long-term necessity of medicating a

chronic illness; such as the use of blood pressure medication to prevent the future onset of heart disease.

Improved access to a more comprehensive primary care benefit for low-income seniors through access to prescription drugs will benefit both state and federal health care programs. Medicare will save from reduced hospitalization rates and Medicaid will realize savings from reduced rates of increase in hospital, nursing home and other medical service utilization.[16] Consequently, a national program that divides the costs of coverage between state and federal governments, like Medicaid, is an important option to provide access to prescription drugs for low-income seniors.

The Department has estimated the potential cost savings under this proposed waiver program. Baseline data is derived using Table 1, which shows historical population and cost data for Wisconsin's Medicaid Aged population for State Fiscal Years (SFY) 1997-2001. Based on preliminary estimates, the Department projects that it will not increase its overall Medicaid expenditures for the Aged population, 65 and older, when increasing primary care benefits by expanding the pharmacy program under this proposal. Budget neutrality will be achieved by reducing the rate of increase in the use of non-pharmacy related services provided to this population including, hospital, nursing facility and other non-pharmacy medical services. The savings realized by reducing the rate of increase in non-pharmacy Medicaid services for this population will offset the costs of expanding the pharmacy benefit under this program.

This cost-effectiveness analysis is conducted by projecting Medicaid expenditures for the Aged population under two separate scenarios. The first scenario, shown in Table 2, projects Medicaid Aged population expenditures, without implementation of the pharmacy waiver. The second scenario, shown in Table 3, projects Medicaid Aged population expenditures, including pharmacy expenditures assuming that the pharmacy waiver program is implemented. The assumptions under each of these scenarios are discussed separately below. Table 3 also compares the projected costs of the Medicaid program with and without the expansion demonstration waiver (SeniorCare). Table 4 shows the estimated cost of the expansion population.

A. Without Implementation of the Pharmacy Waiver Program

Table 2 shows projected Medicaid Aged population expenditures, by year for the five-year demonstration period, assuming that the pharmacy waiver is not implemented. Without the pharmacy waiver program, the Department estimates that Medicaid expenditures for the Aged population, 65 and older, during the five-year demonstration period (SFY 2003-07) will be approximately $8.59 billion.

Amounts shown in Table 2 for the Aged population expenditures are based on actual state fiscal year (SFY) 2001 average expenditure data for all services provided to the Aged population. Per member per month expenditures are increased from SFY 2001

at a rate of 8.67 percent per year, which is based on historical data from SFY 1997-2001.

Average numbers of individuals served are increased from SFY 2001 at a rate of 4.00 percent per year. The estimate for this figure is based upon a variety of factors including:

- Census data, which indicates an increase in the over 65 year-old population and an even greater increase in the over 85 year-old population. A corresponding increase in Medicaid enrollment is projected.[17]

- An increase in Medicaid enrollment due to the recent downturn in the economy.[18]

- An increase in Medicaid enrollment as a result of new outreach efforts for state's Medicaid long-term care demonstration waiver, titled FamilyCare. FamilyCare, under development for several years by the Department, will create a flexible new long-term care benefit and a new way of delivering long-term care services in Wisconsin. The Department has initiated the FamilyCare program and begun providing service in five pilot counties, which will include extensive outreach efforts.

- An increase in enrollment due to SeniorCare publicity and outreach efforts. SeniorCare has received broad media and consumer advocacy attention. The program is projected to enroll an estimated 177,000 Wisconsin seniors. This number represents almost three times the current average annual enrollment for the Medicaid Aged category. The increase in exposure to public programs due to SeniorCare is projected to increase Medicaid enrollment.

- The Social Security Administration (SSA) is conducting a legislatively mandated outreach project to provide information to individuals who may be eligible for the Medicare Savings Programs. These include Qualified Medicare Beneficiaries (QMB), Specified Low-Income Medicare Beneficiaries (SLMB), Qualifying Individuals 1 (QI-1), and Qualified Disabled Working Individuals (QDWI).

  The Beneficiary Improvement and Protection Act was passed on Dec. 21, 2001. Section 1144[1], a new section of the Social Security Act, requires SSA:
  - ✓ to use its records to identify potential Medicare Savings Programs candidates;
  - ✓ to implement annual Medicare Savings Programs outreach notification to identified beneficiaries by December 21, 2002 (one year from enactment);
  - ✓ to at least annually share information with States on potential Medicare Savings Programs beneficiaries; and
  - ✓ General Accounting Office (GAO) to evaluate SSA's efforts.

[1] Section 911 of H.R. 5661, enacted by reference in Public Law 106-554, amended title XI of the Act to include a new section 1144.

SSA will conduct a staggered, outreach mailing beginning in April 2002. An estimated 15 to 18 million letters are to be sent at the rate of 100,000 a day for 6 months. The mailings will be done randomly on a nationwide basis to evenly distribute the workload. We expect to know by the middle of March, the numbers to be mailed to each state.

B. With Implementation of the Pharmacy Waiver Program

The analysis of expenditures with the waiver program includes two components. First, Aged population expenditures were projected taking into consideration reduced Medicaid utilization resulting from anticipated diverted eligibles. Second, expenditures for the demonstration waiver program were estimated. Both of these components are discussed separately.

1. Projected Aged Population Expenditures with Implementation of the Waiver Program

With implementation of the pharmacy waiver, the Department estimates that it will be able to divert from the Medicaid program approximately 3% of Aged Medicaid eligibles from Demonstration Year (DY) 1, 4% from DY 2, and 5% from DY 3, 4, and 5. This estimate is based on the assumption that providing pharmacy benefits will improve the quality of primary health care by preventing catastrophic illnesses requiring institutionalization of people aged 65 and older. As a result, these individuals will become Medicaid-eligible less quickly. It also assumes that those individuals not necessarily at risk of institutionalization will maintain their own financial resources for a longer period of time, making them eligible for Medicaid benefits less quickly.

With this reduction in Medicaid utilization for the Aged population, the Department projects total Medicaid expenditures for the Aged population will be approximately $7.55 billion over the waiver period. This is a cumulative reduction of more than $1.04 billion over the waiver period. Table 3 shows the calculation of Medicaid expenditures for the Aged population taking into consideration the diversion of individuals, but using the same trend rates for expenditures and Medicaid population used in Table 2, which estimates Medicaid cost without the waiver program.

2. Projected Pharmacy Expenditures under the Pharmacy Waiver Program

The Department has projected that when fully implemented SeniorCare will provide pharmacy benefits to approximately 177,000 Wisconsin seniors. It is assumed that full enrollment of these individuals will occur over the course of the first demonstration year. Over the five-year waiver period, the projected total cost of the waiver program is projected to be $1.04 billion.

The Department estimates that net pharmacy expenditures will be approximately $68.95 per member per month for these individuals in the first year of the waiver period. Per member per month costs are projected to increase at an annual rate of 18 percent through the end of the waiver period, increasing to $133.68 per member per month by the fifth year of the waiver period. The net cost for the program is projected to be $116.8 million for Demonstration Year (DY) 01 (SFY 2003). This assumes a ramp-up period for enrollment in the first demonstration year resulting in expenditures of 80% of the annualized total for DY 01. Full enrollment is assumed for DY 02-05.

Net expenditure amounts are adjusted to take into consideration the following projected cost sharing amounts and manufacturers rebates:

- Annual enrollment fees of $20 per year.
- Annual payment of $500 (for certain participants)
- Copayments of $5 and $15 per prescription.
- 18% drug rebates received from manufacturers.

C. Summary of Cost-Effectiveness

With the pharmacy waiver, total combined expenditures for the Aged population and the expanded pharmacy population will not exceed the expenditures that would be incurred for the Aged population without the expanded pharmacy benefit. This expenditure offset will be accomplished by reducing the rate of growth in the Aged population for the waiver period, as a result of the improved health of this population, and by a reduction in the number of individuals in this population that spend down to Medicaid eligibility.

However, an additional and significant benefit of this waiver program, not accounted for in the attached cost effectiveness analyses, is the reduction in expenditures to be realized by the Medicare Program. Similar to savings to be realized by the Medicaid program, it is anticipated that the Medicare program will achieve significant savings through reduced hospitalizations for this population group.

VI. PROGRAM EVALUATION AND MONITORING

A. Principal Research Questions

Wisconsin will address the outcomes of its program by exploring three principal research questions:

1. ***Health*:** Does the waiver program, particularly the pharmacy benefit, improve the health of the low-income elderly population?

2. ***Resources*:** Is there a reduction in the use of non-pharmacy services for program participants as a result of the increased access to necessary medications?

3. ***Health Policy*:** Are the cost savings associated with this program sufficient to influence Medicare or Medicaid policy and planning?

The Department believes that by providing access to prescription drugs, seniors will acquire a basic and cost-beneficial primary care benefit, remain healthier and thereby delay or avoid their eventual enrollment in Medicaid. As discussed in more detail below, using the current data as a baseline, the Department will in part measure the effectiveness of this waiver by a reduction in Medicaid enrollment and expenses, than might otherwise have been the case.

However, measuring the overall change in Medicaid usage will only partially demonstrate the effectiveness of this waiver. In order to evaluate this waiver in a more comprehensive method, the Department intends to also examine the beneficial effect to the *Medicare* program. As a result, the Department further proposes to obtain Medicare current utilization data to use as a baseline, and subsequent data with which to measure cost-effectiveness. As these data are not readily available, the Department may need to partner with CMS to obtain these data on an ongoing basis. The Department believes that measuring the effect on Medicare is vital to demonstrating program effectiveness since much of this population will never become Medicaid eligible due to the waiver program.

Wisconsin's proposed waiver program will offer CMS the opportunity to evaluate the cost-savings for both Medicare and Medicaid, and could serve as a model for a future national drug benefit for seniors. Therefore, extensive quantitative and qualitative monitoring is warranted to identify the outcomes and implications associated with its implementation. The following sections present a framework that may be used by evaluators to analyze the outcomes of this demonstration waiver for the principal questions stated at the beginning of this section.

1. Health

Does the waiver program improve the health of the low-income elderly population covered by the waiver?

The waiver population consists of a mixed group of Wisconsin residents, ages 65 and older. Since health is difficult to quantify and generally declines with age, accurate measurement of the health benefits associated with this demonstration project is complex and difficult. Wisconsin intends to use indirect indicators, such as use of the proposed pharmacy benefit, and survey research methods to

evaluate the outcomes associated with this waiver program. The "health" principles for evaluation and their premises are:

- Prescription drugs are an input to health that the State will be offering to its seniors ages 65 and older, whose income is at or below 240 % of the FPL or those with high drug costs that permit individuals to spend down to program eligibility. The number of seniors, ages 65 and older, eligible for this prescription benefit will serve as a baseline measure and a benchmark for evaluating the success of the program in reaching and enrolling eligible seniors.

- Epidemiological data will be used to evaluate health outcomes for the demonstration population. Medicare data will be used to assess the age-adjusted rates of death associated with acute and chronic diseases treatable with medications. The health outcomes of Wisconsin residents with the pharmacy benefit will be compared to low-income seniors in other states and the nation to evaluate the program's effect.

- Utilization rates will indirectly measure the health outcomes of the waiver participants. The basis of this measure is founded on the assumption that health is associated with reduced use of inpatient hospital services, nursing home care and other medical services provided to the Aged population. Wisconsin, therefore, will monitor pre- and post- demonstration inpatient hospital, nursing home utilization data and other medical services for this population. Rates will be adjusted for patient mix to more accurately assess outcomes associated with the waiver.

2. Resources

Is there a reduction in the use of non-pharmacy services for program participants as a result of the increased access to necessary medications?

Increasing access to prescription benefits will increase the quality of primary care and decrease adverse health outcomes associated with the lack of proper and sufficient medications for this population. Outlays incurred by providing this benefit, therefore, will be offset by the savings generated from fewer hospital and nursing home stays (and other home health/long-term care services) and a possible decrease in emergency room services associated with improper patterns of medication usage. The "resource" principles for evaluation and their premises are:

- Prescription drugs are a medical expense that will decrease inpatient and outpatient hospitalization rates and nursing home and other long-term care services. Prospectively, Wisconsin will collect and compare rates of inpatient and outpatient hospitalizations and nursing home stays between low-income

seniors with and without a prescription drug benefit. Savings associated with the conservation of these healthcare resources will be calculated.

- Proper and sufficient medication routines for some patients with chronic diseases will decrease utilization of emergency room services. Random sampling of demonstration participants' Medicare records will be used to evaluate the waiver's ability to reduce the use of emergency room services for certain disease categories. Evaluators will compare emergency room utilization rates for participants before and after their enrollment into the program.

- Data collected throughout the demonstration will be used to compare medical service costs for people with and without a prescription drug benefit.

- The average Aged population served by Wisconsin Medicaid is projected to increase at an annual rate of 3.0 percent. Trending will monitor the waiver program's ability to maintain or decrease the State's Aged Medicaid enrollment.

- The demonstration program will monitor annual increases in Aged Medicaid expenditures. Historic data suggests that Wisconsin's Aged Medicaid expenditures increase at an annual rate of approximately 6.1 percent. The demonstration program's ability to maintain or decrease this rate, therefore, will validate the demonstration program's success.

3. Health Policy

Are the cost savings associated with this program sufficient to influence Medicare or Medicaid policy and planning?

Many influential factors, such as an aging population and research that makes more medications available to treat a broader range of morbidity, have pressured the United States health care system to realize the importance of providing a more comprehensive primary health care benefit through increased access to pharmaceuticals. As can be seen from research principles and premises previously mentioned, the information gathered during the evaluation process will be useful for future health care policy and planning. Specifically, the "health policy" principles for evaluation and their premises are:

The waiver population consists of citizens at the Medicare qualifying age and, therefore, demonstration outcomes and data will be relevant to the national debate regarding the addition of a Medicare prescription benefit. Cost-effectiveness analysis will yield the value of pharmaceutical interventions for seniors.

The state will have improved the health of its low-income citizens and reduced costs associated with providing care to this segment of the population. This will free up health care dollars that policy makers may allocate to other areas of health care.

B. Waiver Program and the Private Health Insurance Industry

Prescription drug coverage is by far the single most significant gap in coverage for seniors. In addition, supplemental private insurance, whether through former employer-based plans or individually purchased, is becoming more expensive each year. As a result, the number of seniors with supplemental drug coverage is on the decline. SeniorCare is expected to fill an important gap in the medical health insurance offering available to seniors.

With respect to the private health insurance sector, crowd-out can occur if an individual decides to drop private coverage for a public option, or if a pension plan or other private insurer decides to drop or alter coverage for enrollees. However, the waiver program is not expected to have a dramatic effect on the policies of the private health insurance industry or the decision criteria of individuals currently enrolled in the private health insurance sector. The lack of a crowd-out effect is expected for the following reasons:

- Because the waiver program covers a very limited benefit, there are much fewer policies that offer similarly limited coverage. As a result, crowd-out is less of a potential problem simply because there is less to crowd-out.

- Due to the 240% of the FPL limit or spenddown provision, it is not expected that many pension plans will be induced to drop pharmaceutical coverage, since it would leave many enrollees over 240% of the FPL without a viable option for prescription drug coverage.

- Individuals with pension-based coverage of pharmaceuticals usually have the benefit as part of a comprehensive insurance benefit. Because the proposed waiver provides only a pharmacy benefit, there is limited to no incentive for an individual to drop comprehensive insurance for the waiver program.

- The waiver program's cost sharing provisions that are higher than normally found in Medicaid programs. In fact, the cost sharing benefits are similar or even more expensive than those found in private insurance coverage. As a result, there is less individual incentive to drop current coverage for the waiver program.

- As previously mentioned, the Department will use coordination of benefits procedures to provide wrap-around benefits coverage and to pursue payments from other third-party payers.

C. Data Sources

The breadth of this Research and Demonstration project's evaluation will require data from numerous sources. The evaluation will begin at the start of the program and the evaluation process will draw on data for services used prior to and throughout the participants' enrollment in the program. Data on services used prior to enrollment in the demonstration program will allow for the formation of baseline measures and benchmarks. Data sources may include:

- ***Case Study Interviews, Focus Groups and Surveys.*** Structured longitudinal interviews and/or surveys could be used to examine changes in health status and utilization of healthcare services. Surveys or interviews and focus groups could also be used to aggregate information pertaining to perceived changes in quality of life and current and historic utilization of pharmaceuticals. Survey or interview results would be used in conjunction with data obtained from other sources to evaluate the success of this Research and Demonstration project.

- ***Medicare Claims Data.*** This data could be used to assist in establishing changes in utilization patterns for demonstration participants enrolled in Medicare. Medicare's comprehensive database could be used to query data for both waiver and non-waiver participants to evaluate utilization patterns and other relevant factors.

- ***Medicaid Claims Data.*** Medicaid claims data for program participants will provide information regarding participant's demographics, prescriptions filled, total number of waiver participants and waiver expenditures. This data could be cross-referenced with Medicare data.

- ***Vital Statistics Reports and Census.*** Data from entities such as the Department's Divisions of Public Health and Health Care Financing (Bureau of Health Information), the Centers for Disease Control and Prevention, and the Census Bureau will be used for benchmarking. These data can be used to compare outcomes of program participants, such as standardized mortality ratios, to the state as a whole and to the nation.

VIII. PUBLIC INVOLVEMENT, COORDINATION WITH NATIVE AMERICANS, AND PUBLIC NOTICES

A. Public Involvement

Implementation. Public involvement during implementation includes the following:

- The State of Wisconsin has a tradition of open government and extensive public involvement in the design and implementation of major programs, and this

tradition will continue with the development of SeniorCare. There was strong public participation in the design and implementation of BadgerCare, Family Care, and in the statewide expansion of Medicaid managed care.

- The Department has met with key stakeholders, including seniors, providers, the Pharmacy Society of Wisconsin, senior advocacy groups, representatives of the Pharmaceutical Research and Manufacturers of America (PhRMA), and legislators. The feedback we have received to date includes the following points:
  - ✓ All stakeholders expect an on-time and smooth implementation.
  - ✓ Seniors expect a simple and prompt application process that does resemble the Medicaid application process.
  - ✓ Seniors expect excellent customer service.
  - ✓ Pharmacists expect on-line, real time claims processing and accurate payments.

- To assure ongoing communication and coordination with stakeholders, the Department has established a SeniorCare Advisory Committee. The Advisory Committee has met monthly since January 2002, and will continue to meet throughout SeniorCare implementation.

  The SeniorCare Advisory Committee includes representatives from:
  - ✓ Senior advocacy groups (Coalition of Wisconsin Aging Groups, Wisconsin Citizen Action, and AARP);
  - ✓ Benefit specialists (Wisconsin Benefit Specialist Program, Wisconsin Area Agencies on Aging, and the Wisconsin Board on Aging and Long Term Care)
  - ✓ Providers (the State Medical Society of Wisconsin, the Pharmacy Society of Wisconsin, individual pharmacists practicing in Wisconsin, and PhRMA);
  - ✓ Community partners (county and tribal community care representatives); and
  - ✓ State agency representatives (the Wisconsin Departments of Health and Family Services and Administration).

- A series of public meetings and forums will be held to share information, to report on progress, and to provide appropriate training on SeniorCare implementation. Ongoing committees, task forces and association meetings will be used, whenever possible, to facilitate this communication and public involvement.

- Various types of written material will be created to inform the public on an ongoing basis of the State's progress and goals in implementing SeniorCare, such as fact sheets, brochures and media announcements. Two SeniorCare fact sheets have been developed. The fact sheet for potential SeniorCare enrollees is available on the Department's web site.

On Going Operations. Public involvement during ongoing operations includes the following:

The methods of public involvement described above will continue to be used after SeniorCare has been implemented in order to continue to elicit suggestions and ideas for program improvement and to maintain public support for the program. State assessments, evaluations and audits will be shared with the public for this purpose.

B. Coordination with Native Americans

Wisconsin has a long-standing working relationship with tribal health directors in the State. The State has worked closely with tribal health directors on Medicaid HMO implementation, on BadgerCare, and on issues to meet specific tribal health care needs. For instance, a special disenrollment procedure was developed for tribal members that involves close coordination with Indian Health Service Clinics, tribal members, and the Medicaid HMO enrollment broker. A special payment system was developed so that non-HMO affiliated Indian Health Clinics could still be reimbursed by Medicaid fee-for-service funds for services provided to tribal members enrolled in HMOs, so that Indian Health Service funds would not be jeopardized by the expansion of the HMO program.

We continue to hold regular meetings with tribal members to discuss health care related issues. We intend to use these meeting to solicit comments and provide information on SeniorCare.

C. Public Notices

Wisconsin will make the necessary assurances that its 1115 waiver will meet the State notice procedures:

- Notice of Waiver Request

  Wisconsin's Department of Health and Family Services will send stakeholders a copy of this waiver request and stakeholders will be invited to send the Department their comments. This waiver request will also be available on the Department's web site at www.dhfs.state.wi.us.

  Public sessions will be held as described above.

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